

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**UNITED STATES OF AMERICA, *ex rel.*,  
DILBAGH SINGH, M.D.,  
PAUL KIRSCH, M.D.,  
V. RAO NADELLA, M.D., and  
MARTIN JACOBS, M.D.,**

**Relators,**

**v.**

**Civil Action No. 04-186E**

**BRADFORD REGIONAL  
MEDICAL CENTER,  
V&S MEDICAL ASSOCIATES, LLC,  
PETER VACCARO, M.D.,  
KAMRAN SALEH, M.D.,  
and DOES I through XX,**

**Defendants.**

**MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT  
OF BRADFORD REGIONAL MEDICAL CENTER**

Defendant Bradford Regional Medical Center ("BRMC"), through its undersigned attorneys, offers the following in support of its Motion for Summary Judgment.

**I. INTRODUCTION**

**A. Factual Background<sup>1</sup>**

BRMC is a Pennsylvania non-profit corporation. BRMC owns and operates a hospital in Bradford, Pennsylvania which provides inpatient and outpatient hospital services to the residents of McKean County and surrounding areas. Defendant V&S Medical Associates, LLC ("V&S") is a limited liability company, the members of which are Defendants Kamran Saleh, M.D. ("Dr. Saleh") and Peter Vaccaro, M.D. ("Dr. Vaccaro"). Drs. Saleh and Vaccaro are physicians

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<sup>1</sup> References to specific documents supporting this factual summary may be found in BRMC's Concise Statement of Material Facts.

specializing in the practice of internal medicine in Bradford and are members of the medical staff of BRMC. Drs. Vaccaro and Saleh were previously employed by BRMC. In April 2000, Drs. Vaccaro and Saleh left the employ of BRMC by mutual agreement and formed V&S.

The Relators are all physicians who practice in Bradford and are or were members of the medical staff of BRMC. Relators Singh and Nadella practice together. All of the Relators provide the same or similar medical services to patients as Drs. Saleh and Vaccaro.

In 2000, BRMC began to take steps to develop a full-time cardiology program in Bradford. Cardiology services were only available in Bradford one day a week. Patients requiring the services of a cardiologist on any other day would have to travel 90 to 100 miles or more for those services. Not having a full-time cardiology service had an impact on the quality of diagnostics that BRMC could offer to the community, as well as on the quality and type of care that could be provided to patients with acute cardiac problems, high blood pressure and cardiac disease.

The opportunity to recruit a full-time cardiologist to Bradford would be diminished significantly if key cardiology diagnostic services were offered in the offices of internal medicine physicians. Such services would therefore not be available to support the work that the cardiologist would do at the hospital.

After observing the damage done to neighboring hospitals when members of their medical staffs began to compete against these facilities, the Board of Directors of BRMC adopted a resolution in May 2001 establishing a Policy on Physicians with Competing Financial Interests (the "Policy").

Pursuant to the Policy, physicians who had financial relationships with or an ownership or investment interest in, any competing health care services that were determined by the Board to have a significant impact on BRMC could be ineligible for appointment or reappointment to the medical staff of BRMC. The resolution adopting the Policy also stated that, consistent with legal standards, BRMC would use its best efforts to foster cooperative relationships with physicians to facilitate the provision of health care services in the region so that high quality care can be provided in the most cost-effective manner.

In June 2001, V&S entered into a lease agreement with General Electric Healthcare Financial Services for the lease of an SMV SDI Nuclear Camera (the "GE Equipment"). The GE Equipment was subsequently used by V&S to perform nuclear cardiology diagnostic studies on

patients in the offices of V&S. Nuclear cardiology studies are a key type of any diagnostic cardiology service. To the extent that a large medical practice in the community like V&S had a financial incentive to use its own nuclear cardiology equipment instead of BRMC's, it would adversely impact the ability of BRMC to recruit a full-time cardiologist to the community.

In December 2001, the Board of BRMC appointed a fact-finding committee to determine if Drs. Saleh and Vaccaro were in violation of the Policy as a result of their operation of the GE Equipment. The Board sought additional information from Drs. Saleh and Vaccaro as part of this investigation. In January 2002, Drs. Saleh and Vaccaro, through their legal counsel, objected to the Policy and its application to them. Legal counsel for BRMC responded to counsel for Drs. Saleh and Vaccaro in February 2002. There subsequently ensued numerous exchanges between legal counsel for the parties regarding this dispute. In May 2002, the Board of BRMC made a preliminary determination that Drs. Saleh and Vaccaro in fact did have significant competing financial interests pursuant to the Policy, and so informed them of that fact.

In July 2002, in accordance with the prior Board directive to foster cooperative relationships with physicians, BRMC invited Drs. Saleh and Vaccaro, the Relators and other physicians in the Department of Medicine to discuss a potential joint venture (the "Proposed Joint Venture"). The Proposed Joint Venture would be formed by BRMC and interested physicians to provide certain diagnostic imaging services (including nuclear cardiology) under arrangements to BRMC. BRMC engaged a consulting firm known as Stroudwater Associates to perform an analysis of the Proposed Joint Venture.

In the Spring of 2004, BRMC determined not to go forward with the Proposed Joint Venture, in part due to the fact that the Relators refused to participate in it. Three of the Relators subsequently invested in a similar joint venture called Tri-County Diagnostic Testing Services, LLC, which offered cardiology diagnostic services in competition with BRMC.

Meanwhile, between the months of December 2002 and March 2003, several meetings were held between representatives of BRMC and Drs. Saleh and Vaccaro, as well as their respective legal counsel, regarding the possibility of resolving their dispute concerning the Policy. During these meetings, a possible sublease arrangement was also discussed and considered as an option to resolve the dispute while the Proposed Joint Venture was under consideration.

On April 16, 2003, BRMC and V&S entered into an agreement (the "Preliminary Agreement") whereby BRMC would sublease the GE Equipment from V&S, and then use the GE Equipment to provide diagnostic tests for patients of BRMC. V&S would in turn agree to a covenant not to compete with the provision of nuclear cardiology services by BRMC for the term of the sublease. The Preliminary Agreement also contemplated that BRMC could change or upgrade the equipment at its discretion and also required the parties to continue good faith efforts with respect to the development of the Proposed Joint Venture.

During the months of April through September 2003, BRMC and V&S negotiated the specific terms of the sublease agreement as called for by the Preliminary Agreement. In September 2003, the Board of BRMC received a report from Charles T. Day, a certified public accountant, which concluded that the amounts to be paid pursuant to the proposed sublease were reasonable. Effective October 1, 2003, BRMC and V&S entered into an Equipment Sublease (the "Sublease"), which set forth in more detail the terms of the Preliminary Agreement. The Sublease was for a five-year term and is due to expire on September 30, 2008. The Sublease called for BRMC to pay V&S a pass through amount equal to the amounts due from V&S to GE for the GE Equipment plus a monthly amount of \$23,655 for all other rights under the Sublease, including the covenant not to compete. Pursuant to the Sublease, revenues from the performance of nuclear cardiology services were retained by BRMC.

While negotiations regarding the Sublease were being finalized, BRMC determined to replace the GE Equipment with a new nuclear cardiology camera (the "Philips Equipment"). Therefore, the GE Equipment was not relocated to BRMC. Instead, BRMC and V&S entered into a separate agreement for temporary use of the space and services of V&S by BRMC, also effective October 1, 2003 (the "Space and Services Agreement"). The Space and Services Agreement was memorialized in the form of a written proposal and invoice from V&S, which invoice was approved and executed by BRMC's then Chief Financial Officer. The Space and Services Agreement called for BRMC to pay V&S \$2,500 per month for the space where the GE Equipment was located in the offices of V&S, charges for secretarial support, telephone and related services, pass through charges for supplies used in the performance of nuclear cardiology tests, and a billing fee equal to 10% of the amounts collected for nuclear cardiology services.

The Philips Equipment lease was signed on April 6, 2004 and the Philips Equipment began to be used at BRMC under the Sublease. The use of the GE Equipment was discontinued.

The Space and Services Agreement continued through June 2004, in order to collect the outstanding bills for services performed on the GE Equipment, and wind down other related administrative matters.

The buyout of the GE Equipment lease was finally negotiated in December 2004. From January 2005 until the present, the pass-through payments made by BRMC pursuant to the Sublease include the pass through costs for the Philips Equipment, plus the amortized cost of the buyout of the GE Equipment. The payments for the non-compete covenant remain the same.

## **B. Procedural History**

The Relators filed their Complaint under seal on July 2, 2004. (Dkt. No. 1) The United States investigated the matter and declined to intervene on May 11, 2005. (Dkt. No. 6). The Complaint was unsealed and served on the Defendants on July 5, 2005. (Dkt. Nos. 9-12). The Defendants filed a Joint Motion to Dismiss, which was denied by the Court on September 13, 2006. (Dkt. No. 31) Defendants filed their Answers on October 13, 2006. (Dkts. Nos. 35 and 36). Discovery then took place, including the production of documents and responses to interrogatories by all parties. Depositions were taken of the corporate representatives of BRMC pursuant to Rule 30(b)(6), Mr. Leonhardt as an individual, Drs. Saleh and Vaccaro, attorneys Alan Steinberg and Edward Kabala, who respectively represented BRMC and V&S during the Sublease negotiations, all four Relators, and the expert witnesses designated by both sides. BRMC's Motion for Summary Judgment and supporting documentation is now being filed in accordance with the Court's Final Case Management Order. (Dkt. No. 109)

## **II. ARGUMENT**

### **A. Standard of Review**

Under Fed.R.Civ.P. 56(c), summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," demonstrate "no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The party moving for summary judgment has the initial burden of showing the basis for its motion. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

The burden then shifts to the nonmovant to come forward with specific facts showing a genuine issue for trial. Matsushita Elec. Indus. v. Zenith Radio Corp., 475 U.S. 574 (1986);

Williams v. Borough of West Chester, Pa., 891 F.2d 458, 460-461 (3d Cir.1989) (non-movant must present more than a scintilla of affirmative evidence to support his claims). The non-moving party must do more than rest upon mere allegations, general denials, or vague statements. Rather, "the party opposing the motion must go beyond its pleadings and designate specific facts by use of affidavits, depositions, admissions, or answers to interrogatories showing there is a genuine issue for trial." In re Ikon Office Solutions, 277 F.3d 658, 666 (3d Cir. 2002). A genuine issue is one in which the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The Relators cannot show that there is any genuine issue for trial for the reasons set forth below.

### **B. Summary Judgment Should Be Granted in Favor of BRMC**

The Relators' Complaint contends that the Sublease violates the so-called Stark Law, 42 U.S.C. § 1395nn, and the Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b). Based on this contention, the Relators go on to allege that BRMC submitted false claims to Medicare, Medicaid and CHAMPUS/Tricare for services performed on patients referred by Drs. Saleh and Vaccaro, in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.*<sup>2</sup> The Relators' claims are primarily based on a "false certification" theory, which contends that because the claims for reimbursement and/or cost reports submitted to those programs by BRMC (allegedly) contain certifications that BRMC is in compliance with the law, and because (allegedly) the Sublease violated the law, all of the claims for payment for services provided to the patients of Drs. Saleh and Vaccaro who are covered by those programs are false.<sup>3</sup> Complaint pp. 23-25, Second and Third Causes of Action. In addition, the Relators contend that because the Sublease allegedly violated the Stark law and Anti-kickback Statute, claims submitted by BRMC were in violation

<sup>2</sup> Relators must ultimately prove that there was a violation of the False Claims Act in order to prevail, since there is no private right of action under the Anti-kickback Statute. West Allis Memorial Hospital v. Bowen, 852 F.2d 251, 254-255 (7th Cir. 1988). Similarly, Relators lack standing to pursue a claim for a violation of the Stark Law. U.S. ex rel. Repko v. Guthrie Clinic, 557 F. Supp. 2d. 522, 529 (M.D.Pa. 2008).

<sup>3</sup> This false certification theory cannot prevail with respect to any Medicaid or CHAMPUS/Tricare claims, since the cost reports filed by BRMC with those programs do not contain any certifications, unlike the Medicare cost reports. (Nadella Deposition pp. 53-60, Exs. 4, 5). Likewise, contrary to the Relators' allegations, the Medicare claims forms submitted by BRMC on a routine basis do not contain any certifications. Therefore, BRMC is entitled to summary judgment on the false certification theories advanced by Relators in their Second and Third Causes of Action, at least to the extent that they rely on the nonexistent certifications in Medicaid and CHAMPUS cost reports or the UB-92 claims forms submitted to Medicare.



of the False Claims Act. Complaint p. 23, First Cause of Action. Relators also claim that BRMC conspired with the other defendants to submit these allegedly false claims. Complaint p. 25, Fourth Cause of Action.

However, it is the claims of the Relators in this case which are false. For the reasons set forth below, BRMC is entitled to summary judgment on the Relators' claims.

# **1. The Sublease and Other Financial Relationships Between BRMC and V&S Do Not Violate the Stark Law**

The Stark Law generally prohibits physicians from making referrals for certain "designated health services" ("DHS") payable by Medicare<sup>4</sup> to an entity (such as a hospital) with which the physician (or an immediate family member) has a financial relationship. 42 U.S.C. § 1395nn(a)(1)(A). The law also prohibits the entity from filing claims for payment with Medicare for services referred by such physicians. 42 U.S.C. § 1395nn(a)(1)(B). These prohibitions are not applicable if certain statutory or regulatory exceptions apply. 42 U.S.C. § 1395nn(b) through (e).

## **(a) The Stark Law Does Not Apply**

The preamble to the so-called Phase II<sup>5</sup> Stark Regulations, promulgated by the Centers for Medicare & Medicaid Services ("CMS"), states: "The existence of a financial relationship between the referring physician...and the entity furnishing DHS is the factual predicate for triggering the application of [the Stark Law]." 69 Fed. Reg. 16057. The term "financial relationship" is described by the Stark Law as including "ownership or investment interests" and "compensation arrangements." 42 U.S.C. § 1395nn(a)(2). The term "compensation arrangement" is defined as meaning any arrangement involving remuneration between the physician or family member and the entity to which referrals are made. 42 U.S.C.

<sup>4</sup> The Stark Law's prohibitions were extended to Medicaid in 1993. 42 U.S.C. § 1396b(s). The law does not apply to any other federal health care program, such as CHAMPUS/Tricare. For this reason, BRMC is also entitled to summary judgment to the extent that Relators have alleged that claims submitted to programs other than Medicare and Medicaid violate the False Claims Act due to alleged violations of the Stark Law.

<sup>5</sup> The Stark Regulations, as they exist today, were promulgated over a number of years in three "phases." The Phase I regulations were published on January 4, 2001. 66 Fed. Reg. 856 *et seq.* The Phase II regulations were published on March 26, 2004. 69 Fed. Reg. 16054 *et seq.* The Phase III regulations were published on September 5, 2007. 72 Fed. Reg. 51012 *et seq.* In addition, some additional changes that will go into effect on October 1, 2008 and 2009 were published on August 19, 2008 as part of the Fiscal Year 2009 Medicare Hospital Inpatient Prospective Payment Systems regulations (the "IPPS regulations"). See 73 Fed. Reg. 48688-48740; 48751-48754. Due to their complex nature, it is often necessary to refer to regulatory text and comments in all three phases as well as the IPPS regulations to fully understand the Stark Regulations.

§ 1395nn(h)(1)(A). That term is further defined in the Stark Regulations as described in more detail below.

In this case, the Stark law simply does not apply to the relationships between BRMC and V&S that the Relators have attacked. This is because the relationships between BRMC and V&S (a corporate entity) are neither direct nor indirect financial relationships between BRMC and either Dr. Saleh or Dr. Vaccaro *as individuals*. Furthermore, even if the transactions between BRMC and V&S were found to constitute indirect relationships, or deemed to be direct financial relationships between BRMC and Drs. Saleh and Vaccaro, those transactions would fit within the statutory and regulatory exceptions for permitted relationships. Thus, Drs. Saleh and Vaccaro are not prohibited from referring Medicare or Medicaid patients to BRMC, and BRMC is not prohibited from submitting claims to Medicare or Medicaid for services provided to those patients.

The Stark Regulations define the term "financial relationship" as including: "A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS. 42 C.F.R. § 411.354(a)(ii). The regulations go on to state that: "A direct compensation arrangement exists if remuneration passes between the referring physician...and the entity furnishing DHS *without any intervening persons or entities*." (Emphasis added.) 42 C.F.R. § 411.354(c)(1)(i). This obviously cannot apply to the Sublease and the other transactions challenged by the Relators, since they are between BRMC and V&S, not Drs. Saleh and Vaccaro as individuals.

The definition of "indirect compensation arrangements" is somewhat more complicated. An indirect compensation relationship exists if: (i) there exists an unbroken chain of persons or entities that have financial relationships between them; (ii) the referring physician receives aggregate compensation from the person or entity with whom the physician has a direct financial relationship that varies with or takes into account the volume or value of referrals or other business generated by the physician; and (iii) the entity furnishing DHS has actual knowledge of or acts in reckless disregard or deliberate ignorance of the fact that the physician's compensation so varies. 42 C.F.R. § 411.354(c)(2)(i) to (iii).<sup>6</sup>

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<sup>6</sup> The Phase III regulations amended 42 C.F.R. § 411.354(c)(3) by adding a new subsection (iv), which provides that a physician will "stand in the shoes" of his or her "physician organization" and be deemed to have the same relationships with any entity to which the physician refers patients for designated health services that the physician organization has. A "physician organization" was defined by 42 C.F.R.



BRMC will concede that the Sublease and the other financial relationships with V&S are part of an "unbroken chain" between BRMC and Drs. Saleh and Vaccaro as described in the Stark regulations, by virtue of their ownership of V&S. However, the crucial second and third elements of the definition of "indirect compensation arrangement" are missing. The amounts paid by BRMC under the Sublease and the other financial relationships to V&S in no way vary with or take into account the volume or value of referrals of or other business generated by Drs. Saleh and Vaccaro. Thus, any compensation received by Dr. Saleh or Vaccaro by virtue of the arrangements between BRMC and their professional corporation (V&S) could also not so vary based on their referrals. In addition, the record is devoid of any evidence to show that BRMC knew or could have known how Dr. Saleh or Vaccaro were paid by V&S.<sup>7</sup>

The critical term in the definition which leads to the inescapable conclusion that the Sublease and other arrangements do not give rise to a financial relationship between BRMC and Drs. Saleh and Vaccaro for Stark purposes is "varies with or takes into account the volume or value of referrals or other business generated by the physician." This language, which appears throughout the Stark Regulations, is often referred to as "the volume or value standard." The payments under the Sublease and other arrangements were fixed. They did not fluctuate up or down based on how many or how few patients were referred to BRMC by Dr. Saleh or Vaccaro. The Relators may suggest that because various documents and statements of the Defendants mention referrals, the arrangement must take referrals into account. But such an interpretation of the volume or value standard would be incorrect as a matter of law.

The Stark Regulations set forth a simple, bright-line test for determining whether compensation varies with or takes into account referrals. According to the Phase I rules: "A compensation arrangement does not take into account the volume or value of referrals or other

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§ 411.351 as including a physician practice such as V&S. However, the stand in the shoes provisions do not apply during the original term or current renewal term of an arrangement, such as the Sublease, that was in existence as of September 5, 2007. These regulations were further refined by the IPPS Regulations to only require the stand in the shoes rule to apply to the owners of a physician organization. 73 Fed. Reg. 48752.

<sup>7</sup> The remainder of the discussion on this point will focus on the second element of the indirect compensation arrangement definition. However, it should suffice to point out that summary judgment is appropriate in False Claims Act cases predicated on alleged Stark Law violations when relators cannot show any evidence that a hospital had any knowledge of how an entity with which it contracts paid the physicians who refer to the hospital. U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, 2008 W.L. 2791687 at \*16 (D.D.C. 2008).

business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated." 66 Fed. Reg. 877-878. In the recent case of U.S. ex rel. Villafane v. Solinger, 543 F.Supp.2d 678 (W.D. Ky. 2008), the court affirmed this interpretation and rejected the notion that the subjective intent of the parties should determine whether the volume or value standard applied.<sup>8</sup> According to the court:

...where no violation appears on the face of the arrangement, either in the form of above-fair-market value compensation or of a provision allowing for increases or decreases in payment based on the number of referrals made, the text and history of the Stark law's desire to create a "bright-line rule" would seem to argue against establishing a violation on the basis of intent alone.

Id. at 693.

The Sublease establishes on its face that the rental payments from BRMC to V&S do not vary based on the amount of business that either Dr. Saleh or Dr. Vaccaro generates for BRMC. Section 2(d) calls for flat monthly rental payments. There is no evidence that Relators can point to that payments fluctuated in any manner based on referrals.<sup>9</sup> Thus, the only other question is whether the amounts paid reflect the fair market value of what was exchanged. However, even though they have the burden of proof of establishing that the Stark Law applies, Relators have offered no evidence that the amounts paid under the Sublease are above fair market value. In fact, their expert specifically disclaimed having any opinion on the market value of amounts paid pursuant to the various arrangements between BRMC and V&S, or even being qualified to render any such opinion. Barbera Deposition, pp. 81, 123.

Relators' expert did offer testimony about his opinion concerning the commercial reasonableness of the Sublease, but this testimony is irrelevant to whether the Stark Law applies,

<sup>8</sup> The court was analyzing the volume or value standard in the context of whether the "academic medical center" exception set forth in 42 C.F.R. § 411.355(e) applied, but CMS has made it clear since the Phase I regulations that the volume or value standard should be subject to a uniform interpretation regardless of which section of the Stark Regulations is in question. 66 Fed. Reg. 877.

<sup>9</sup> The pass-through costs paid for the equipment did change when the Philips Equipment was brought on line, but this was in no way related to referrals. The Phase I regulations specifically state that a "cost plus" methodology is a reasonable way to establish fair market value for equipment rentals, so a straight pass through would presumptively not exceed fair market value. 66 Fed. Reg. 877.

since commercial reasonableness is not a factor in determining whether an indirect compensation arrangement exists or if one does exist, whether it falls within the exception for indirect compensation arrangements. Furthermore, responding to commenters in the preamble to the Phase II regulations, CMS made it clear that "commercial reasonableness," in terms of the various exceptions that require it, means an arrangement that would make commercial sense to a similar type and size entity and a reasonable physician, even in the absence of referrals. 69 Fed. Reg. 16093. As has been demonstrated by BRMC, the hospital had a clear interest in developing a full-time cardiology service. To that end, entering into the arrangement in order to obtain a non-compete from V&S was a sensible, prudent business arrangement.

Likewise, the fact that the Sublease contains a non-compete covenant does not mean that the payments vary with or take into account the volume or value of referrals, according to the CMS interpretation set forth in the preamble to the Phase I Stark Regulations. Responding to commenters who were concerned that the volume or value standard would call into question covenants not to compete, CMS allayed this concern, stating: "A requirement to refer to a specific provider is different from an arrangement not to establish a competing business." 66 Fed. Reg. 878-879. Relators' expert confirmed that at his deposition when asked if he was "contending that the non-compete clause would require Dr. Saleh or Vaccaro to refer patients to BRMC, he responded "No." Barbera Deposition at p. 115.

**(b) Even if the Stark Law Did Apply, the Sublease and Other Arrangements Would Be Permitted by Regulatory Exception**

Assuming *arguendo* that there was an indirect compensation arrangement between BRMC and Drs. Saleh and Vaccaro, it would still meet the exception for indirect compensation arrangements, which applies if:

- (1) The compensation received by the referring physician...is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.
- (2) The compensation arrangement...is set out in writing, signed by the parties, and specifies the services covered by the arrangement....

- (3) The compensation arrangement does not violate the anti-kickback statute...or any Federal or State law or regulation governing billing or claims submission.

42 C.F.R. § 411.357(p).

As explained above, any compensation received by Drs. Saleh and Vaccaro as a result of the Sublease and other arrangements with BRMC is not determined in any manner that takes into account the volume or value of their referrals to BRMC. In fact, the record establishes that Drs. Saleh and Vaccaro own equal membership interests in V&S. Saleh Deposition, p. 6. The various arrangements are all set out in writing and signed by both parties, and specify what is covered by the arrangement. And, as explained below, the arrangements fit within the "safe harbors" under the Anti-kickback Statute, so they would meet the definition of the phrase "does not violate the anti-kickback statute" as defined in the Stark Regulations. 42 C.F.R. § 411.351.<sup>10</sup>

## **2. The Sublease and Other Arrangements Between BRMC and V&S Fit Within the Anti-kickback Safe Harbors**

The Anti-kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce referrals of items or services reimbursable by any federal health care program. 42 U.S.C. § 1320-7b(b)(1) and (2). However, this prohibition does not apply to "any payment practice specified by the Secretary [of HHS] in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987." 42 U.S.C. § 1320-7b(b)(3)(E). These regulations are commonly referred to as "safe harbor" regulations. If an arrangement fits within the safe harbors, the intent of the parties in entering into the arrangement is irrelevant, since the arrangement is excluded from the prohibitions of the statute. The safe harbor regulations contain provisions that clearly apply to and permit the Sublease and other arrangements between BRMC and V&S.

Safe harbor regulations were promulgated in 1991, and amended in 1999, covering space rental, equipment rental and personal services and management contracts. 42 U.S.C. § 1001.952(b) through (d). They have remained the same ever since. When applied to the Sublease and the other arrangements between BRMC and V&S, it is clear that these arrangements are not only common business practices, they are perfectly legal. Relators have offered no evidence to suggest otherwise.

<sup>10</sup> Relators have not alleged, nor have they offered any proof, that the arrangements between BRMC and V&S violate any Federal or State law or regulation governing billing or claims submission.

The Sublease fits squarely within the equipment rental safe harbor which applies as long as the following standards are met:

- (1) the lease agreement is set out in writing and signed by the parties;
- (2) the agreement covers all of the equipment leased between the parties for the term of the agreement and specifies the equipment covered by the lease;
- (3) if the agreement is intended to provide the lessee with access to the space for periodic intervals of time rather than on a full-time basis for the term of the rental agreement, the rental agreement specifies exactly the schedule of such intervals, the precise length of each interval, and the exact rent for each interval;
- (4) the term of the rental agreement is for not less than one year;
- (5) the aggregate rental charge is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program;
- (6) the aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

42 U.S.C. § 1001.952(c).

As noted above, the various arrangements are all set out in writing and signed by both parties. The terms of the Sublease cover the GE Equipment and specifically contemplate that the equipment may be changed or upgraded during the term of the arrangement. Sublease, Section 5. Therefore, under the equipment rental safe harbor, the Philips equipment that was later acquired is also covered by the Sublease. The term of the agreement was set at five years and, as has been clearly shown, the aggregate payments do not take into account the volume or value of any referrals. Finally, as evidenced in the Defendant's expert report, the aggregate payments do not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

Likewise, the temporary arrangement whereby BRMC leased space in the offices of V&S pursuant to the Space and Services Agreement fit within the space rental safe harbor, which requires that virtually identical standards to those in the equipment rental safe harbor be met. 42 U.S.C. § 1001.952(b).

For the same reasons, the provisions of the Space and Services Agreement pursuant to which V&S provided support services for BRMC while the GE Equipment was located in the offices of V&S fit within the safe harbor for personal services and management contracts, which requires that:

- (1) the agreement is in writing and signed by the parties;
- (2) the agreement specifies the services to be provided;
- (3) if the agreement is intended to be for services on a periodic, sporadic, or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
- (4) the term of the agreement is for not less than one year;
- (5) the aggregate compensation paid over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program; and
- (6) the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

42 U.S.C. § 1001.952 (d).

### III. CONCLUSION

For the foregoing reasons, BRMC respectfully requests that summary judgment be entered in its favor and against the Relators, and that the Relators' Complaint be dismissed, with prejudice.



September 10, 2008

Respectfully submitted,



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Daniel M. Mulholland III  
Pennsylvania ID No. 28806

HORTY, SPRINGER & MATTERN, P.C.  
4614 Fifth Avenue  
Pittsburgh, PA 15213  
Phone: (412) 687-7677  
Fax: (412) 687-7692  
[dmulholland@hortyspringer.com](mailto:dmulholland@hortyspringer.com)

Attorney for Defendant  
Bradford Regional Medical Center

### CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this date he served the following with a copy of the foregoing Memorandum in Support of Motion for Summary Judgment by e-mail via the Court's ECF system and by first class United States mail, addressed as follows:

Andrew M. Stone, Esquire  
Allegheny Building, Suite 1400  
429 Grant Street  
Pittsburgh, PA 15219

G. Mark Simpson, Esquire  
Simpson Law Firm, LLC  
165 North Main Street  
Jonesboro, GA 30236

Carl J. Rychcik, Esquire  
Fox Rothschild, LLP  
625 Liberty Avenue, 29th Floor  
Pittsburgh, PA 15222

Paul E. Skirtich, Esquire  
Assistant U.S. Attorney  
Western District of Pennsylvania  
U.S. Post Office & Courthouse  
700 Grant Street, Suite 4000  
Pittsburgh, PA 15219

September 10, 2008



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Daniel M. Mulholland III